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K053016

DEC 30 2005

5 510(k) Summary

Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614-5686
Contact Person:	Diane Peterson Project Manager, Regulatory Affairs
Date Prepared:	October 24, 2005
Trade name:	Wireless Physiologic Monitoring System
Classification Name:	o Transducer, Pressure, Catheter tip (21 CFR 870.2870) o Transmitters and receivers, physiological signal, radiofrequency (21 CFR 870.2910)
Predicate Devices:	o Phoenix Disposable Pressure Transducer #73-600 o SurgiChip Tag Surgical Marker o M3290A IntelliVue Information Center Software Rel. F.0 and M4840A Telemetry System II with M4841A TelePac+ o MPT 24 and VitalView 24
Device Description:	The Edwards Lifesciences' Wireless Physiologic Monitoring System replaces the existing cabling between disposable blood pressure transducers and bedside monitors in hospital settings. The wireless link allows the system to support all transducer performance requirements and specifications currently supported with a direct cable connection. Existing system cabling connectors are retained in the event that all available channels are filled, or in the unlikely event that issues are found in particular situations that preclude the use of the wireless connection. The Wireless Physiologic Monitoring System utilizes two types of wireless technology to provide a convenient solution for replacing cabling between the

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	disposable pressure transducer and the patient monitor. Radio Frequency Identification (RFID) is utilized as a convenient method to initially setup the system, and the Wireless Medical Telemetry Service band (WMTS) is used for the continuous transmission of data from the transducers to the monitor during normal operation.
Intended Use:	The Wireless Physiologic Monitoring System is indicated for use on patients requiring pressure monitoring. The Wireless Physiologic Monitoring System is intended to perform wireless transmission of pressure information to remote patient monitors from disposable pressure transducers.
Comparative Analysis:	The Wireless Physiologic Monitoring System has been demonstrated to be as safe and effective as the predicate devices for its intended use.
Functional/Safety Testing:	The Wireless Physiologic Monitoring System has successfully undergone functional testing as well as electrical safety testing. This product has been shown to be equivalent to the predicate devices.
Conclusion:	The Wireless Physiologic Monitoring System is substantially equivalent to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 30 2005

Edwards Lifesciences LLC
c/o Ms. Diane Peterson
Project Manager, Regulatory Affairs
One Edwards Way
Irvine, CA 92614

Re: K053016
Trade Name: Wireless Physiologic Monitoring System
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II (two)
Product Code: DXO
Dated: October 24, 2005
Received: October 26, 2005

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known):

Device Name: Wireless Physiologic Monitoring System

Indications for Use:

The Wireless Physiologic Monitoring System is indicated for use on patients requiring pressure monitoring. The Wireless Physiologic Monitoring System is intended to perform wireless transmission of pressure information to remote patient monitors from disposable pressure transducers.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053016